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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,437	11/14/2003	J. Francois Eid	EID-P-1	7044

44702 7590 09/01/2005

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EXAMINER

GILBERT, SAMUEL G

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/713,437	Applicant(s) EID, J. FRANCOIS	
	Examiner Samuel G. Gilbert	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 1,4-6 and 8-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/14/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

In order to avoid abandonment, the drawing informalities noted in the paper mailed on 12/17/2004, must now be corrected. Correction can only be effected in the manner set forth in the above noted paper.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 - it is unclear what device dimension is being set forth by the "size" set forth in the claim.

Claim 6 - the claim sets forth the numbers and grooves are on the handle. The examiner believes the numbers and grooves are position on the shaft not the handle as shown in the drawings.

Claim 26 - "the shaft opening" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19 and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fishell(4,653,485).

Claim 17 - element -10- is a cylinder, the examiner is taking the inside portion of element -10- surrounding ball -32a- as a cradle, a fluid reservoir is not shown but set forth in column 3, line 33. Element -12- is a means for connecting. Fishell does not set forth a pump chamber or means for controlling. However it is the examiners position that both are inherently required to perform the controlled filling of the chambers -19- to provide an erection as is intended by the device of Fishell.

Claim 18 - silicone is set forth, column 4 line 6.

Claim 19 - the cradle is joined by an adhesive, column 3 lines 46-54.

Claim 21 - it is the examiner's position that the silicone used is a soft silicone.

Claim 22 - the method is set forth in column 4 lines 25-50.

Claim 23 the aperture is inherently smaller than required by an inflated cylinder because the device is inserted in a deflated state.

Claim 24 - since only a small incision is used postoperative scarring is decreased.

Claim 25 - tool -30- is used to insert the implant.

Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohamad(5,484,450). Mohamad teaches a device as shown in figures 3 and 5, including a shaft -120-, handle -110-, and a receptacle -122-. The receptacle includes a notch -124-, surface -132- is convex. The device is similarly dimensioned to the applicant's device therefore the examiner believes the device is dimensioned as claimed. The element -120- may be bent to angle away from the handle depending on the desired use, column 4 lines 25-30.

Regarding the prior art set forth in Mohamad figure 1 and the description in column 1 lines 42-54, the outside surface of element -12- is convex while the inside surface is concave.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485).

Claim 20 - In the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art. In the instant case the selection of 5mm distance from

the distal end of the cradle would have been an obvious design expedient to one of ordinary skill in the art.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485) in view of Thompson (5,643,288).

Claim 1 - Fishell teaches a device -30- including an elongate body -32- having a handle -38- and a hole -34- or -36- at apposing end -32a-(receptacle). The surfaces are smooth. Fischell does not teach an angled shaft or a handle and shaft in spaced and parallel relation. Thompson teaches a surgical instrument for retrieving a suture having a straight handle and shaft or a shaft spaced and offset from the handle. Applicant's attention is invited to figure 11 and column 43-61. The changing of the shaft shape is desirable to make the surgical procedure easier, as taught by Thompson. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an offset parallel shaft in the device of Fishell to make the insertion of the penile prosthesis easier as taught by Thompson. The procedure would be easier because an offset handle would be able to be turned to be out of the line of sight of the user and the handle could be grasped more easily because it would not be as close to the abdomen.

Claim 4 - the diameter of the elongated body is .25 inches which is within the claimed range. The outside of the sphere -32a- is convex.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell (4,653,485) Thompson (5,643,288) as applied to claim 1 above and further in view of

Furlow et al (4,244,370). Fishell teaches a device as claimed but does not teach measurement calibrated on the device. Furlow et al teaches an implantation device having measurement calibrations -16-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include calibrations as taught by Furlow et al with the device of Fishell to gain the advantage of being able to determine the depth of the device as taught by Furlow et al.

Claims 6, 9, 10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohamad(5,484,450) in view of Furlow et al (4,244,370).

Mohamad teaches a device as shown in figure 5, including a shaft -120-, handle -110-, and a receptacle -122-. The receptacle includes a notch -124-. Mohamad does not teach etched numbers and grooves to permit precise positioning of the prosthesis. Furlow et al teaches an implantation device having measurement calibrations -16- to allow proper positioning of the implant and to prevent accidental perforations(set forth in Buckley(5,109,869). The examiner is taking official notice that it is old and well known to include numbers with calibration grooves. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include etched numbers and grooves on the device of Mohamed, including the handle, to allow the user to easily determine the depth of implantation and to prevent perforations as taught by Furlow et al and Buckley. Numbering the grooves allows the user to determine depth while the device is being used.

Claim 9 – the device has smooth edges and finish to protect against damage.

Claim 10 the receptacle is about 10mm in cross section, column 3, lines 5-12.

Claim 12 – the device of Mohamad is capable of performing the recited function.

Claims 13-16 - applicant's attention is invited to figure 1 and the description in column 1 lines 42-54. Surface -132- is convex, column 3 lines 33-34. The examiner is unclear as to the exact structural limitation the applicant is trying to claim with respect to "dimensioned to conform to the configuration of the prosthesis, however because Mohamad has a dimension and is used with a penile prosthesis the examiner believes the device of Mohamad is dimensioned to conform to the prosthesis as claimed.

Claims 6, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishell(4,653,485) in view of Furlow et al (4,244,370).

Fishell teaches a device -30- including an elongate body -32- having a handle -38- and a hole -34- or -36- at apposing end -32a-(receptacle). Fishell does not teach etched numbers and grooves to permit precise positioning of the prosthesis. Furlow et al teaches an implantation device having measurement calibrations -16- to allow proper positioning of the implant and to prevent accidental perforations(set forth in Buckley(5,109,869). The examiner is taking official notice that it is old and well known to include numbers with calibration grooves. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include etched numbers and grooves on the device of Fishell, including the handle, to allow the user to easily determine the depth of implantation and to prevent perforations as taught by Furlow et

al and Buckley. Numbering the grooves allows the user to determine depth while the device is being used.

Claim 8 - the end sphere -32a- is being considered to be convex, fusiform (tapered on the distal and proximal end of the sphere) and smooth edge and finish.

Claim 10 - Fishell teaches a device as claimed as set forth above with regard to claim 6. However the dimensions for the entire device is not set forth. The shaft is .25 inches but the dimension for the end ball is not set forth. The ball is larger than the shaft but the exact dimension is not set forth. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select any size as long as the selected dimension would be capable delivering the implant to the desired implantation site. In the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art. In the instant case the selection of .39 inches diameter for the ball, 3/8 inches, would be slightly larger than .25 inches and would be within the expected range for the ball of Fishell.

Claim 11 - is replete with functional language that does not result in a structural difference between the claim and the prior art device. The device of Fishell is capable of conforming and supporting as claimed.

Allowable Subject Matter

Claims 26 and 27 are allowed.

Response to Arguments

Regarding the objection to the drawings, the applicant argues that every conceivable element does not have to be graphically depicted. The objection set forth by the examiner does not request an illustration of every possible/conceivable element only every feature specified in the claims as required by 37 CFR 1.83(a).

Regarding the rejection of claim 17 over Fishell the applicant argues element -32a- is a cradle which is not on the distal tip of the cylinder. The examiner would like to point out that the examiner is taking the ***inside portion of element -10-*** surrounding ball -32a- as a cradle not the ball(element -32a- itself).

Regarding the arguments directed to Mohamad, the outside surface of element -12- is convex while the inside surface is concave. Further, the device is dimensioned to conform to the configuration of the prosthesis.(the examiner is unclear as to what structure this limitation is directed to, however because both devices are used for penile prosthesis implantation it is the examiner's position that the device is so dimensioned)

Regarding the applicant's arguments directed to the inherency of the pump chamber and the control means, the examiner would like to point to column 3 lines 31-31 where a fluid source is set forth and the fluid is delivered under pressure. The examiner believes that this inherently requires a pump chamber(some place to hold the fluid) and control means to deliver the fluid under pressure.

Regarding the arguments directed to the change of size of the devices; the examiner would like to point out that the dimensions of the particular structure of the prior art devices are not set forth, however the devices are all used and therefore are required to fit within the penis in which the device will be used. In the absence of showing any criticality for the particularly selected size the selection of any size within the range of sizes generally accepted for the device (in this case sizes that will fit in the penis) would be an ordinary design expedient to one of ordinary skill in the art. Further, it is well settled that a change in size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Samuel G. Gilbert
Primary Examiner
Art Unit 3736

Sgg
8/30/2005